January 5, 2009

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Re: FDA-2008-D-0525
Draft Guidance for Industry on "New Contrast Imaging Indication Considerations for Devices and Approved Drug and Biological Products"

Dear Sir or Madam,

Olympus America Inc., is an importer, distributor, Official Correspondent and US Agent for OLYMPUS MEDICAL SYSTEMS CORP. Olympus manufactures and markets medical imaging devices, which include Endoscopes and Ultrasound Endoscopes (EUS). Currently, these medical imaging devices are not being used in combination with a medical imaging drug. However, use of theses devices in combination with medical imaging agents are currently under development. This guidance can be a useful tool not only for existing medical imaging technologies and medical imaging drugs, but also for new medical imaging technologies currently under development.

Background Medical Imaging Technology

Lines 121-123 (Draft Dated 10•01•08): We agree that medical imaging technology includes ultrasound, computerized tomography, magnetic resonance imaging and traditional radiology. However, medical imaging technology also includes endoscopy and ultrasound endoscopy. These medical imaging technologies are currently not included in this section. This may lead to confusion as to if this guidance would be applicable in the future if endoscopes and ultrasound endoscopes are used in combination with an imaging drug. We recommend clarification to the guidance as to which types of medical imaging technologies or devices will be covered under the scope of this guidance.

Premarket Development Considerations

Lines 312-314 (Draft Dated 10•01•08): We concur with comments that have already been submitted by Medical Imaging & Technology Alliance (MITA) [FDA-2008-D-0525-0007]. We also believe that there may be circumstances in which a medical imaging device investigation may be a non-significant risk study. In addition, we request further clarification on the various clinical pathways that may be acceptable for a medical imaging device manufacturer if they wish to add a new contrast indication. For example, if a manufacturer of medical imaging drug or an independent investigator performs a clinical trial (IND) to investigate the use of the imaging drug for a new contrast indication or to expand the indication to be used with additional legally marketed medical imaging device or device(s), this data may be sufficient for a medical imaging device manufacturer to pursue the new contrast indication through the appropriate marketing submission and without sponsoring their own clinical study.

Type of Marketing Submission – PMA or 510(k)

Lines 46-54, 294-296, 406-416, (Draft Dated 10•01•08): We concur with the comments that have already been submitted by the Academy of Molecular Imaging (AMI) [FDA-2008-D-0525-0004] and MITA [FDA-2008-D-0525-0007]. There are may be situations in which a medical imaging device has already been predicated as Class II and calling for premarket clearance. For these devices, in which little or no modification is required for a new contrast indication, a PMA may not be an appropriate pathway and a 510(k) may be more appropriate. Also, the *De Novo* pathway may also be a consideration for

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circumstances in which the new contrast indication for a medical imaging device has no clear predicate and when special controls alone may be adequate to provide a reasonable assurance of safety and effectiveness.

As this guidance document has the potential to impact device, drug and biologic manufactures and as the imaging technologies and agents can drastically vary, we would also like to encourage FDA to hold discussions with the various industries before releasing a final guidance. We appreciate the opportunity to comment on this draft guidance as the draft guidance has the potential to be a valuable tool for medical imaging products. Please feel free to contact me at 484-896-5405 or by email at stacy.kluesner@olympus.com.

Sincerely,

Stacy Abbatiello Kluesner, M.S., RAC
Regulatory Affairs Project Manager
Olympus America Inc.